**Official Title(s):**

"An online parenting intervention for families affected by substance misuse in pediatric primary care"

Clinical Trials Registration Number: NCT06273228

Document: Primary Consent Form

Date: 3-19-2024

# Consent for Research Participation

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| **Title:** | Parenting Young Children in Pediatrics |
| **Sponsor:** | National Institute on Drug Abuse (NIDA) P50 Center on Parenting and Opioids, University of Oregon |
| **Researcher(s):** | Kate Hails, Ph.D., Elizabeth Stormshak, Ph.D. (University of Oregon) |
| **Researcher Contact Info:** | Phone: 541-203-0824<br>khails@uoregon.edu |

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

**Key Information for You to Consider**

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this study is to provide parenting support through a smartphone-based program called the Family Check Up Online (FCU Online) to parents who have young children in pediatric primary care and are navigating past or current substance misuse. Parents will have access to additional support and encouragement from a Family Consultant over phone, text, or Zoom. Another purpose is to understand how pediatric primary care practices can provide additional support for parenting and managing child behavior for parents who are interested in these resources.
- **Duration.** It is expected that your participation will last approximately 7-8 hours across 3 months.
- **Procedures and Activities.** You will be invited to participate in the following activities:
  - Internet surveys- Two internet surveys, one at the beginning of the study, and one 3 months later that take between 30 to 60 minutes to complete. The surveys will ask about you, your feelings, your health, your family, and parenting your child. You will be paid $75 for each internet survey, and that can be paid by check or electronic gift card to Amazon. If you prefer, the survey may also be completed as an interview.
  - FCU Online- You will be asked to use the FCU Online on your smartphone to think about parenting and practice new skills. The topics covered include wellness and self-care, parenting and substance use, positive parenting, proactive parenting, and rules and limit setting. You can expect to spend about 60 minutes a week using the FCU Online. The FCU Online will occur over approximately 5 weeks.
  - Phone support from a Family Consultant- A Family Consultant will support you in setting goals and using the FCU Online through phone calls, text, or Zoom check-ins. You will complete check-in appointments with your Family Consultant for each of the 5 topics in the FCU Online. Each check-in will take approximately 20 minutes and will be audio recorded.
  - Interview- At the end of the study, you may be asked to complete a phone interview about what you liked and what can be improved about the FCU Online and Family Consultant support. The interview will also ask you whether and how you would like to learn about and receive the FCU Online from a provider in your child's pediatrician's office. You will be paid $75 for completing the interview. This interview would take 30-60 minutes and will be audio-recorded.

- **Risks.** Some of the foreseeable risks or discomforts of your participation include feeling uncomfortable answering some questions in the phone interviews or talking with your Family Consultant. You can choose not to respond to questions in the interviews. There is also a risk that your private information could be revealed. However, we take precautions to guard against this.
- **Benefits**. Some of the benefits that may be expected include enjoying thinking about parenting and practicing new skills. You may enjoy talking to your Family Consultant about your goals and getting support on parenting.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.
- *A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.*

**Who is conducting this research?**

The researchers Kate Hails, Ph.D. and Elizabeth Stormshak, Ph.D. from the University of Oregon are asking for your consent to this research.

Beth Stormshak, a co-investigator, is founder of Northwest Prevention Science, Inc., a for-profit entity that provides consultation and training services on the Family Check Up. Kate Hails, the principal investigator, is a consultant who provides consultation and training services through Northwest Prevention Science, Inc. Research on the Family Check Up may contribute to and inform the services Drs. Stormshak and Hails provide through Northwest Prevention Science, Inc. As a result, Dr. Stormshak, Dr. Hails, and Northwest Prevention Science, Inc. may financially benefit from this research. Questions about this may be directed to Dr. Hails.

**Why is this research being done?**

The purpose of this pilot study is to evaluate a smartphone-based program for parents with young children. The program relies on the Family Check-Up (FCU), a family-based intervention that has been used in schools, in homes, and at the University of Oregon Prevention Science Institute, for the past 25 years. Recently the FCU was developed to be delivered online with coaching. This study will help guide the development of the FCU as a telehealth model to be delivered to families by behavioral experts in their children's pediatricians' offices.

You are being asked to participate because you are a parent with a child between the ages of 10 months and 5 years old who receives their pediatric primary care at PeaceHealth Pediatrics or Oregon Health & Science University. About 36 people will take part in the study. About 9 people will be offered an opportunity to participate in interviews at the end of the study. Interviews will be conducted via phone or HIPAA-compliant Zoom.

**How long will I be in this research?**

We expect that your participation will last approximately three months.

**What happens to the information collected for this research?**

Information collected from this study will be used to help us ensure our smartphone-based program is easy for parents to use, and a helpful resource for dealing with some of the stress that comes with parenting young children. Your survey responses will be kept private, and audio recordings of check-in sessions will be kept private and stored on a secure server.

Your survey responses and opinions are kept private and only reported in summary. No names will be used in any summaries of the study findings. Data from this study will be securely stored locally at UO before being de-identified and submitted to a centralized data repository for the Center on Parenting and Opioids (CPO). Deidentified study data means that all personal information about you (such as name, address, birthdate and

phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about health more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the centralized repository, which will be hosted by the University of Oregon (UO), Oregon Health and Sciences University (OHSU), or the National Institute on Drug Abuse (NIDA) which is a branch of the National Institutes of Health (NIH). Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the UO and OHSU who know how to keep your data safe will review each request carefully to reduce risks to your privacy. You will not be contacted directly by other researchers about the study data you contributed to the CPO repository.

In addition, your deidentified data may be shared with additional investigators for future research studies without additional informed consent from you or your legally authorized representative.

Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

**How will my privacy and data confidentiality be protected?**

Your surveys are given unique study ID numbers, so your name is not linked to your responses. Research records, including your consent form and the key linking identifiable information to your unique study ID number, will be retained for five years through the end of the study, and will be destroyed at the end of the study.

Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected.

We will take measures to protect the security of all your personal information including storing consent forms, surveys collected via Qualtrics, and video and audio recordings of any sessions with Family Consultants on our secure server. Staff conducting phone interviews or Zoom interviews are trained to protect participant privacy. Data stored on our server is password protected and access will be limited to authorized staff. Despite these precautions to protect the confidentiality of your information, we can never fully guarantee confidentiality of all study information.

Individuals and organization that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your consent form or audio recording. These individuals and organizations include: The Institutional Review Board (IRB) that reviewed this research; The National Institutes of Health (NIH), the study sponsor.

The research team includes individuals who are mandatory reporters. If the research team has reasonable cause to suspect abuse or neglect of a child or adult, a report may be required under Oregon State Law. In such a case, the research team may be obligated to breach confidentiality and may be required to disclose personal information. We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal,

state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.

**What if I want to stop participating in this research?**

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researchers or the University of Oregon.

**Will I be paid for participating in this research?**

In this study, you may be paid up to $150 if you complete all components: the initial internet survey and another survey 3 months later. We will also be offering a random selection of families the opportunity to participate in a phone interview at the end of the study. You would be paid $75 for completing the interview. There will be no cost to you or your insurance company to participate in this study.

**Who can answer my questions about this research?**

If you have questions, concerns, or have experienced a research related injury, contact the research team at:

Kate Hails, PI
Phone: 541-203-0824
Email: khails@uoregon.edu

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510
ResearchCompliance@uoregon.edu

**STATEMENT OF CONSENT**

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

I consent to participate in this study.

| Name of Adult Participant | Signature of Adult Participant | Date |
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